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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,632	12/05/2003	Michael O'Connor	OCNNOR-07998	1115

7590 01/24/2005

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EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,632	<b>Applicant(s)</b> O'CONNOR ET AL.	
	<b>Examiner</b> Nikita R Veniaminov	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 55-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55,56,58,64 and 67-74 is/are rejected.
- 7) ☒ Claim(s) 57,59-63,65 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/20/2004</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on 09/20/2004 was considered by the examiner.

### *Terminal Disclaimer*

2. The terminal disclaimer filed on 09/20/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,685,622 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 55, 56, 58 and 64** are rejected under 35 U.S.C. 102(b) as being anticipated by Magill (US 1,251,258). Magill ('258) teaches a method comprising:

**Claim 55 (independent)**

- a) providing a device for maintaining an area in an isolated environment (A), said device (A) comprising an enclosure (1) for separating said area from an atmosphere ambient to said device (A), a means for evacuating said isolated environment (9), a means (13) for refilling said isolated environment, and at least one access port (7), wherein said area is chosen from an injured area (page 2, lines 9-14); and
- b) positioning the device over said area and releasably attaching said device to a patient's skin surrounding said area (page 1, lines 9-38);

**Claim 56**

wherein said injured area is selected from the group consisting of burns and lesions (page 1, lines 9-14);

**Claim 58**

the method of Claim 55, further comprising step

- c) evacuating any gas within said isolated environment (page 1, lines 69-80) by using said means for evacuating (9).

**Claim 64 (independent)**

A method comprising:

- a) providing a device for maintaining an area in an isolated environment (A), said device (A) comprising an enclosure (1) for separating said area from an atmosphere ambient to said device (A), a means for filling (13) said isolated

Art Unit: 3736

environment, and at least one access port (16), wherein said area is chosen from an injured area (page 2, lines 9-14); and

b) positioning the device over said area and releasably attaching said device to a patient's skin surrounding said area (page 1, lines 9-38).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 67-74** are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (US 5,730,777) in view of Csete et al. (US 6,184,035).

Peterson et al. ('777) teach a method comprising:

**Claim 67 (independent)**

a) providing a device (Figures 1 and 2 – a housing with chambers; column 18, lines 42-67) for maintaining biological material, such as cell cultures, biologic DNA or RNA, etc. (column 8, lines 54-59) in an isolated environment, said device comprising an enclosure (a housing on Figure 1 having chambers with walls 1-4) for separating said biological material from an atmosphere ambient to said device, a means for evacuating said isolated environment (column 18, line 60), and a means for refilling (Figure 1(6) and column 18, lines 61-66) said isolated

Art Unit: 3736

environment, wherein the oxygen tension of said isolated environment is controllable (column 18, line 67 and column 19, lines 1-3); and

b) placing said biological material in said device (column 21, lines 5-27);

**Claim 68**

the method of claim 67, wherein said means for evacuating comprises means for oxygen release and retention of a heavy gas within said isolated environment (column 9, lines 52-55 and column 18, lines 58-60);

**Claim 69**

the method of claim 67, wherein said means for evacuating produces an environment with reduced oxygen tension (column 9, lines 52-55 and column 18, lines 58-60);

**Claim 70**

the method of claim 67, wherein said means for refilling produces an environment with reduced oxygen tension (column 19, lines 21-54 and column 9, lines 54-66);

**Claim 71**

the method of claim 67, wherein said means for refilling produces an environment with an increased oxygen tension (column 12, lines 37-61);

**Claim 72**

the method of claim 67, wherein said isolated environment is essentially pathogen-free (column 14, lines 57-62);

**Claim 73**

the method of claim 67, wherein said transplant material is selected from the group consisting of cells, and artificial materials (column 8, lines 50-60);

**Claim 74**

the device of claim 67, wherein said device is suitable for transporting said biological material (Examiner states, that the device on Figure 2 is capable for transporting said biological material).

But Peterson et al. ('777) do not teach a transplant material.

Csete et al. ('035) teach a method of isolating and maintaining stem cells derived from diverse organ or tissue sources, that can be accomplished by the controlled use of subatmospheric oxygen culture (abstract). Physiologic or low oxygen culturing of cells can be established by using commercially-available chambers (column 6, lines 15-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use cells as a transplant material of Csete et al. ('035) in the method of Peterson et al. ('777) to provide oxygen-controlled isolated environment for intact functioning tissue or cells, as taught by Csete et al. ('035).

***Allowable Subject Matter***

7. **Claims 57, 59-63, 65 and 66** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art, either alone or in combination, teaches or suggests a method, as claimed, wherein at least one access port is suitable for admission of at least one surgical means selected from the group consisting of surgical instruments, robotics, sensors, and human hands; or a method, as claimed, comprising step d) introducing sterile gas within an isolated environment by using means for evacuating.

None of the prior art, either alone or in combination, teaches or suggests a method, as claimed, wherein either a means for filling produces an environment with reduced oxygen tension; or wherein a means for filling produces an environment with an increased oxygen tension.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sundheim et al. ('437); Hyman ('713); Smith et al. ('724); Barbieri ('387); Hopkins et al. ('450); Jessamine et al. ('710); Sarason ('442); McMillan ('155); Trexler ('809); Elledge et al. ('925); Folsom et al. ('753); Benetti et al. ('569); Mayer ('719); Mutke ('728); Henry ('333); Rotheberg ('414); Orchard et al. ('217); Mutke ('728); Dutton et al. ('415); Henry ('333); Petersen et al. ('017) and Fischer ('541).



***Response to Arguments***

10. Applicant's arguments, see **RESPONSE TO OFFICE ACTION**, filed on 09/20/2004, with respect to the rejection(s) of **claims 55-58 and 63-74** under the judicially created doctrine of obviousness-type double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Magill (US 1,251,258); Peterson et al. (US 5,730,777) and Csete et al. (US 6,184,035).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

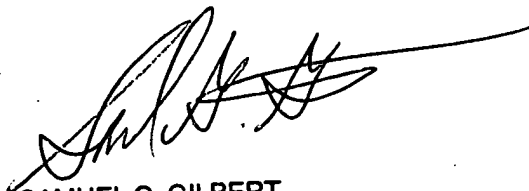
Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov  
Examiner  
Art Unit 3736

November 26, 2004.



SAMUEL G. GILBERT  
PRIMARY EXAMINER